ET10-166

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Federal Communications Commission
Office of the Secretary

Ms. Marlene Dortch
Secretary
Federal Communications Commission
445 12th Street, N.W.
Washington, D.C. 20554

Re: ANSYS Inc., - Request for Waiver of 47 C.F.R. § 1.1307(b)(2)

Dear Ms. Dortch:

Pursuant to Sections 1.3 and 1.925 of the Commission's Rules, 47 C.F.R. §§ 1.3, 1.925, this is a request on behalf of Ansys, Inc., for a waiver of Section 1.1307(b)(2) of the Commission's Rules, 47 C.F.R. § 1.1307(b)(2), to permit routine environmental evaluation of medical implant or body-worn equipment authorized for use in the Medical Device Radiocommunication Service (MedRadio) by finite element method (FEM) computational modeling.

Background. ANSYS develops and globally markets engineering simulation software and technologies for use by engineers, designers, researchers and students across a broad spectrum of industries and academia. Founded in 1970 and headquartered in Canonsburg, PA, the company currently employs more than 1,600 people and it distributes its products in over 40 countries. ANSYS has been the pioneer for finite element modeling. It is the developer of High Frequency Structure Simulator ("HFSS"), a FEM-based software tool for simulation testing.

Currently, Section 1.1307(b)(2) of the Commission's rules restricts routine environmental evaluation for RF exposure of equipment transmitting in the MedRadio Service to actual laboratory measurement techniques or finite difference time domain ("FDTD") computational modeling. The effect of this rule is to prohibit reliance on HFSS as an acceptable computational modeling tool for MedRadio equipment authorization, to the economic detriment of ANSYS. ANSYS believes the Commission's rule is unduly and unnecessarily restrictive, since FEM is capable of simulating fundamental physics identical to that of FDTD, while operating on a different technological basis.

The amendment of Section 1.1307(b)(2) to require routine environmental evaluation of medical implant transmitters by means of either laboratory measurement or FDTD computational modeling occurred in 1999 with the establishment of the Medical Implant Communications Service (MICS). *In the Matter of Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant Communications Service in the 402-405 MHz Band,* Report and Order, FCC 99-363, released November 29, 1999 ("*MICS Order*"), ¶ 12. In its adopting order, the Commission attributed its decision to require evaluation for RF exposure prior to MICS equipment authorization to a joint *ex parte* filing by Medtronic, Inc. and Dr. William Scanlon of the University of Ulster. The order included no discussion of whether evaluation should be restricted to laboratory measurement or whether simulation modeling would be permitted or, if modeling were to be permitted, what modeling technologies could be utilized.

Examination of the June 18, 1999 *ex parte* filing, a copy of which is attached to this request as Attachment A, reveals the inclusion of proposed amending language for both Sections 1.1307(b)(2) and 95.603(f) of the Commission's Rules. The *ex parte* proposal for amending Section 1.1307(b)(2) included the requirement, ultimately adopted by the Commission, for the use of either laboratory measurement or FDTD modeling, although the joint presentaton offered no discussion regarding the efficacy of this modeling technique. The *ex parte* filing further proposed that Section 95.603(f) of the Commission's Rules be amended to include the following: "Medical implant transmitters (as defined in Appendix 1 to Subpart E of Part 95 of thie chapter) are subject to the radiofrequency radiation exposure requirements specified in §§ 1.1307 and 2.1093 of this chapter, as appropriate. Applications for equipment authorization of devices operating under this section must contain a finite difference time domain (FDTD) computational modeling report showing compliance with these provisions for fundamentel emissions." The Commission adopted this proposal, as well, in its *MICS Order* as part of then-Section 95.603(g) of its Rules. Significantly, in adopting both of these rule changes, the Commission offered no analysis or evaluation of why FDTD merited its regulatory imprimatur for environmental evaluation purposes.

In March 2009, the Commission replaced and superseded MICS with its new MedRadio Service, which enlarged the operational spectrum for the new service by two Megahertz. *In the Matter of Amendment of Parts 2 and 95 of the Commission's Rules to Establish the Medical Device Radiocommunication Service at 401-402 and 405-406 MHz*, Report and Order, FCC 09-23, released March 20, 2009 ("*MedRadio Order*"). Former Section 95.603(g) of the Commission's Rules was replaced with the current version of 95.603(f) of the Rules, which requires simply that all MedRadio transmitters require certification in order to be marketed in the United States, but it relegated the standards for how certification would actually be accomplished to other sections of the Rules, thereby eliminating the reference in that Rule to FDTD. Section 1.1307(b)(2) was retained materially in the form it had existed since issuance of the *MICS Order*, with the exception that the reference to MICS was replaced by one to MedRadio. In the *MedRadio Order*, the Commission acknowledged Medtronic's request that unspecified "other techniques" (beyond the finite difference time domain (FDTD) technique cited in the existing rules) "could be used for equipment authorization and RF exposure evaluation purposes." However, it concluded that insufficient notice had been provided for consideration of this question, and deferred the question to another proceeding which it deemed "better suited" to address RF exposure issues in a more comprehensive context. *MedRadio Order*, ¶¶ 67-68.

<u>*Request for Waiver*</u>. Against this background, ANSYS submits that the Commission's current endorsement in its rules of FDTD as an acceptable modeling technique for RF exposure evaluation purposes to the exclusion of other modeling techniques is based on a deficient administrative record. ANSYS has conducted a literature search which presents scientific evidence that FEM is recognized and utilized in the industry as a simulation modeling technique of equal merit and credibility to FDTD. The results of ANSYS' investigation are submitted in support of this waiver request as Attachment B. This attachment includes a summary explanation of how each scientific article presented supports ANSYS' position that FEM merits recognition by the Commission as a simulation tool comparable in effectiveness to FDTD. FEM is capable of simulating fundamental physics identical to that of FDTD while operating on a different but equally valid technological basis.

In this connection, it is to be noted that both FDTD and FEM are currently under review by the IEEE International Committee for Electromagnetic Safety (ICES) Technical Committee (TC) 34 Subcommittee (SC) 2. In this subcommittee, representatives of the Commission, the FDA, international agencies, wireless handset manufacturers and software manufacturers are establishing Recommended Practices for the evaluation of electromagnetic safety from wireless communication devices by means of FDTD and FEM. The draft Recommended Practices for both of these techniques have yet to be submitted to the IEEE Standards Committee for consideration. Therefore, as of this time, neither of these techniques has received formal acceptance by the industry standards-setting body, and cannot be differentiated from one another on that basis.

The current distinction in the Rule between FDTD and FEM is not technologically defensible. The Commission might ultimately wish to consider a rule change to amend Section 1.1307(b)(2) to permit the use of simulation modeling on a more generic basis. In the meantime, however, ANSYS is suffering a competitive disadvantage in the marketplace in its efforts to commercialize HFSS for MedRadio applications due to the Rule's current restrictive text. It would not be fair, and should be unnecessary, for ANSYS to have to wait for the Commission to launch and conduct an entire rulemaking process in order to have its technology recognized on an equal regulatory footing with FDTD. More expeditious relief could be made available were the Commission instead to grant ANSYS a waiver of Section 1.1307(b)(2) to permit FEM modeling techniques to be employed for RF exposure evaluation equally with both FDTD and laboratory measurement.

Section 1.3 of the Rules, 47 C.F.R. § 1.3, permits the Commission to waive a rule "for good cause shown." Section 1.925(b)(3) of the Rules, 47 C.F.R. § 1.925(b)(3), specifies that the Commission may grant a request for waiver if it is shown that:

> (i) The underlying purpose of the rule(s) would not be served or would be frustrated by application to the instant case, and that a grant of the requested waiver would be in the public interest; or
>
> (ii) In view of unique or unusual factual circumstances of the instant case, application of the rule(s) would be inequitable, unduly burdensome or contrary to the public interest, or the applicant has no reasonable alternative.

In the present case, good cause exists for the Commission to grant the waiver requested by ANSYS, and both the standards outlined in Section 1.925 of the Rules are met. As the Commission explained in its *MICS Order*, the amendment of Section 1.1307(b)(2) was undertaken to require evaluation prior to equipment authorization in order to safeguard against excessive human exposure to RF emissions. *MICS Order*, ¶¶ 11-12. By permitting an equally valid modeling technique to be used in competition to FDTD, the Commission will expand the availability of engineering testing methodologies for medical device manufacturers, thereby enabling them to negotiate for lower costs in their development streams which will ultimately benefit their end users. In this manner, the requested waiver will advance both the purpose of the rule and the public interest. In addition, the waiver will rectify the current inequitable treatment of ANSYS and other users of FEM technology and will implement Section 1.1307(b)(2) in a more technologically neutral fashion. *See In the Matter of Revision of the Commission's*

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Rules to Ensure Compatibility with Enhanced 911 Emergency Calling Systems, 20 FCC Rcd. 7709, 7714-15 (2005).

ANSYS has stated its waiver request with clarity and has accompanied the request with supporting data. Under these circumstances, the Commission should follow prevailing judicial guidance that "a general rule, deemed valid because its overall objectives are in the public interest, may not be in the "public interest" if extended to an applicant who proposes a new service that will not undermine the policy, served by the rule, that has been adjudged in the public interest." *WAIT Radio v. Federal Communications Commission*, 418 F.2d 1153, 1157 (D.C. Cir. 1969). ANSYS has demonstrated it has an equally sound technological solution to fulfill the public purpose for which the use of FDTD modeling techniques was originally recognized in the Commission's Rules. Under these circumstances, special circumstances warrant deviating from the general rule in the public interest. *In the Matter of Intel Corporation, Motorola, Inc., TiVo, Inc.*, Memorandum Opinion and Order, DA 10-1094, released June 18, 2010 (Media Bureau).

<u>Conclusion</u>. The recognition of FDTD by name, to the exclusion of other modeling techniques in Section 1.1307(b)(2), was accomplished on the basis of a deficient administrative record. The Commission now has the opportunity to mitigate the effects of that procedural shortcoming. Grant of ANSYS' request for waiver to permit the use of FEM modeling techniques for RF exposure evaluation will advance, rather than frustrate, the underlying purpose of the Rule, and will benefit the public interest by expanding the universe of suppliers of modeling techniques. At the same time, it will overcome the inequity that the current language of the Rule fosters, and will advance technological neutrality. For all these reasons, ANSYS' request for waiver should be granted.

Sincerely yours,

D.D.S

Delbert D. Smith
Counsel for Ansys, Inc.

Attachments (as indicated)

cc: Julius Knapp
Bruce Romano
Ed Mantiply

WAI-2974298v1

June 18, 1999

Ms. Magalie Roman Salas, Secretary
Federal Communications Commission
The Portals, TW-A325
445 12th Street, S.W
Washington, DC 20554

Re: Ex Parte Presentation
WT Docket 99-66 – Medical Implant Communications Service

Dear Ms. Salas:

We are writing to address the matter of the Commission's proposal to exempt from routine RF exposure evaluation the transmitters that would be used in medical implant devices to be authorized under the rules proposed in WT Docket 99-66. As the record in this proceeding will reflect, we have presented differing points of view on the need for the routine submittal of a showing in support of compliance with the RF exposure guidelines prior to the issuance of a grant of equipment authorization for medical implant transmitters.

After Medtronic had filed its position on the issue, we discussed this matter. The ensuing conversation centered around antenna technologies that could be used on medical implants and how each technology could influence RF exposure of the patient. Although Medtronic has pointed a system for which the finite difference time domain (FDTD) modeling conducted by Medtronic shows a substantial margin of compliance, the Medtronic approach may not be the only one employed for medical implant transmitters. A different technology, such as an electrically short antenna, can have strong localized reactive fields. It was also recognized that other manufacturers will develop their own designs and that other technologies could potentially cause SAR levels at or near the current limits. In view of the discussion, we have reached a consensus that it would be appropriate, due to the potential impact of differing technologies on RF exposure, for the Commission to require routine filing of an FDTD computational modeling report with each application for certification of a medical implant transmitter. Filing of this type of report will provide additional assurance that the patient's health and safety are protected and will serve to provide a "yardstick" for determination of the need for the Commission to exercise its authority to require actual SAR measurements. To this end, we are attaching recommended revisions to Section 1.1307 of the Commission's rules and to Section 95.603 of the proposed rules.

ATTACHMENT A

We hope that this joint submittal will help to clarify the record in this proceeding and assist the Commission as it works to conclude this rule making.

Respectfully,

Dr. William Scanlon
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Eduardo Villaseca
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Medtronic, Inc.
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Enclosure
cc: Mr. Eugene Thomson (FCC/WTB) (w/ encl.)

Proposed Revisions to Section 1.1307 of the FCC Rules

Revised language is shown in **bold underlined** text.

§1.1307 Actions that may have a significant environmental effect, for which Environmental Assessments (EAs) must be prepared.

(a) *Commission actions* with respect to the following types of facilities may significantly affect the environment and thus require the preparation of EAs by the applicant (see §§1.1308 and 1.1311) and may require further Commission environmental processing (see §§1.1314, 1.1315 and 1.1317):

(1) Facilities that are to be located in an officially designated wilderness area.

(2) Facilities that are to be located in an officially designated wildlife preserve.

(3) Facilities that: (i) May affect listed threatened or endangered species or designated critical habitats; or (ii) are likely to jeopardize the continued existence of any proposed endangered or threatened species or likely to result in the destruction or adverse modification of proposed critical habitats, as determined by the *Secretary of the Interior* pursuant to the Endangered Species Act of 1973.

NOTE:
The list of endangered and threatened species is contained in 50 CFR 17.11, 17.22, 222.23(a) and 227.4. The list of designated critical habitats is contained in 50 CFR 17.95, 17.96 and Part 226. To ascertain the status of proposed species and habitats, inquiries also may be directed to the Regional Director of the Fish and Wildlife Service, Department of the Interior.

(4) Facilities that may affect districts, sites, buildings, structures or objects, significant in American history, architecture, archeology, engineering or culture, that are listed, or are eligible for listing, in the National Register of Historic Places. (See 16 USC 470w(5); 36 CFR Parts 60 and 800.)

NOTE:
The National Register is updated and republished in the *Federal Register* each year in February. To ascertain whether a proposed affects an historical property of national significance, inquiries also may be made to the appropriate State Historic Preservation Officer, see 16 USC 470a(b); 36 CFR Parts 63 and 800.

(5) Facilities that may affect Indian religious sites.

(6) Facilities to be located in a flood plain. (See Executive Order 11988.)

(7) Facilities whose construction will involve significant change in surface features (e.g., wetland fill, deforestation or water diversion). (In the case of wetlands on Federal property, see Executive Order 11990.)

(8) Antenna towers and/or supporting structures that are to be equipped with high intensity white lights which are to be located in residential neighborhoods, as defined by the applicable zoning law.

(b) In addition to the actions listed in paragraph (a) of this section, Commission actions granting construction permits, licenses to transmit or renewals thereof, equipment authorizations or modifications in existing facilities, require the preparation of an Environmental Assessment (EA) if the particular facility, operation or transmitter would cause human exposure to levels of radiofrequency radiation in excess of the limits in §§1.1310 and 2.1093 of this chapter. Applications to the Commission for construction permits, licenses to transmit or renewals thereof, equipment authorizations or modifications in existing facilities must contain a statement confirming compliance with the limits unless the facility, operation, or transmitter is categorically excluded, as discussed below. Technical information showing the basis for this statement must be submitted to the Commission upon request.

(1) [See Bulletin OET 65 and 65A] The appropriate exposure limits in §1.1310 and §2.1093 of this chapter are generally applicable to all facilities, operations and transmitters regulated by the Commission. However, a determination of compliance with the exposure limits in §1.1310 or §2.1093 of this chapter (routine environmental evaluation), and preparation of an EA if the limits are exceeded, is necessary only for facilities, operations and transmitters that fall into the categories listed in Table 1, or those specified in paragraph (b)(2) of this section. All other facilities, operations and transmitters are categorically excluded from making such studies or preparing an EA, except as indicated in paragraphs (c) and (d) of this section. For purposes of Table 1, "building-mounted antennas" means antennas mounted in or on a building structure that is occupied as a workplace or residence. The term "power" in column 2 of Table 1 refers to total operating power of the transmitting operation in question in terms of effective radiated power (ERP), equivalent isotropically radiated power (EIRP), or peak envelope power (PEP), as defined in §2.1 of this chapter. For the case of the Cellular Radiotelephone Service, Subpart H of Part 22 of this chapter; the Personal Communications Service, Part 24 of this chapter and the Specialized Mobile Radio Service, Part 90 of this chapter, the phrase "total power of all channels" in column 2 of Table 1 means the sum of the ERP or EIRP of all co-located simultaneously operating transmitters owned and operated by a single licensee. When applying the criteria of Table 1, radiation in all directions should be considered. For the case of transmitting facilities using sectorized transmitting antennas, applicants and licensees should apply the criteria to all transmitting channels in a given sector, noting that for a highly directional antenna there is relatively little contribution to ERP or EIRP summation for other directions.

Table 1 - Transmitters, Facilities and Operations Subject to Routine Environmental Evaluation

Experimental Radio Services (Part 5)	Power > 100 W ERP (164 W EIRP)
Multipoint Distribution Service (Subpart K of Part 21)	Non-building-mounted antennas: height above ground level to lowest point of antenna < 10 m and power > 1640 W EIRP Building-mounted antennas: power > 1640 W EIRP MDS licensees are required to attach a label to subscriber transceiver or transverter antennas that: (1) provides adequate notice regarding potential radiofrequency safety hazards, e.g., information regarding the safe minimum separation distance required between users and transceiver antennas; and (2) references the applicable FCC-adopted limits for radiofrequency exposure specified in §1.1310.
Paging and Radiotelephone Service (Subpart E of Part 22)	Non-building-mounted antennas: height above ground level to lowest point of antenna < 10 m and power > 1000 W ERP (1640 W EIRP) Building-mounted antennas: power > 1000 W ERP (1640 W EIRP)
Cellular Radiotelephone Service (Subpart H of Part 22)	Non-building-mounted antennas: height above ground level to lowest point of antenna < 10 m and total power of all channels > 1000 W ERP (1640 W EIRP) Building-mounted antennas: total power of all channels > 1000 W ERP (1640 W EIRP)

Personal Communications	(1) Narrowband PCS (Subpart D): Services (Part 24) non-building-mounted antennas: height above ground level to lowest point of antenna < 10 m and total power of all channels > 1000 W ERP (1640 W EIRP) Building-mounted antennas: total power of all channels > 1000 W ERP (1640 W EIRP) (2) Broadband PCS (Subpart E): non-building-mounted antennas: height above ground level to lowest point of antenna < 10 m and total power of all channels > 2000 W ERP (3280 W EIRP) Building-mounted antennas: total power of all channels > 2000 W ERP (3280 W EIRP)
Satellite Communications (Part 25)	All included
General Wireless Communications Service (Part 26)	Total power of all channels > 1640 W EIRP
Wireless Communications Service (Part 27)	Total power of all channels > 1640 W EIRP
Radio Broadcast Services (Part 73)	All included
Experimental, auxiliary, and special broadcast and other program distributional services (Part 74)	Subparts A, G, L: power > 100 W ERP Subpart I: non-building-mounted antennas: height above ground level to lowest point of antenna < 10 m and power > 1640 W EIRP Building-mounted antennas: power > 1640 W EIRP ITFS licensees are required to attach a label to subscriber transceiver or transverter antennas that: (1) provides adequate notice regarding potential radiofrequency safety hazards, e.g., information regarding the safe minimum separation distance required between users and transceiver antennas; and (2) references the applicable FCC-adopted limits for radiofrequency exposure specified in §1.1310
Stations in the Maritime Services (Part 80)	Ship earth stations only
Private Land Mobile Radio Services Paging Operations (Part 90)	Non-building-mounted antennas: height above ground level to lowest point of antenna < 10 m and power > 1000 W ERP (1640 W EIRP) Building-mounted antennas: power > 1000 W ERP (1640 W EIRP)
Private Land Mobile Radio Services Specialized Mobile Radio (Part 90)	Non-building-mounted antennas: height above ground level to lowest point of antenna < 10 m and total power of all channels > 1000 W ERP

	(1640 W EIRP) Building-mounted antennas: Total power of all channels > 1000 W ERP (1640 W EIRP)
Amateur Radio Service (Part 97)	Transmitter output power > levels specified in §97.13(c)(1) of this chapter
Local Multipoint Distribution Service (Subpart L of Part 101)	Non-building-mounted antennas: height above ground level to lowest point of antenna < 10 m and power > 1640 W EIRP Building-mounted antennas: power > 1640 W EIRP. LMDS licensees are required to attach a label to subscriber transceiver antennas that: (1) provides adequate notice regarding potential radiofrequency safety hazards, e.g., information regarding the safe minimum separation distance required between users and transceiver antennas; and (2) references the applicable FCC-adopted limits for radiofrequency exposure specified in §1.1310 of this chapter

(2) Mobile and portable transmitting devices that operate in the Cellular Radiotelephone Service, the Personal Communications Services (PCS), the Satellite Communications Services, the General Wireless Communications Service, the Wireless Communications Service, the Maritime Services (ship earth stations only) and the Specialized Mobile Radio Service authorized under Subpart H of Parts 22, 24, 25, 26, 27, 80 and 90 of this chapter are subject to routine environmental evaluation for RF exposure prior to equipment authorization or use, as specified in §§2.1091 and 2.1093 of this chapter. Unlicensed PCS, unlicensed NII and millimeter wave devices are also subject to routine environmental evaluation for RF exposure prior to equipment authorization or use, as specified in §§15.253(f), 15.255(g), and 15.319(i) and 15.407(f) of this chapter. **Equipment authorized for use in the Medical Implant Communications Service (MICS) as a medical implant transmitter (as defined in Appendix 1 to Subpart E of Part 95 of this chapter) is subject to routine environmental evaluation for RF exposure prior to equipment authorization, as specified in §2.1093 of this chapter by finite difference time domain computational modeling or laboratory measurement techniques. Where a showing is based on computational modeling, the Commission retains the discretion to request that specific absorption rate measurement data be submitted.** All other mobile, portable, and unlicensed transmitting devices are categorically excluded from routine environmental evaluation for RF exposure under §§2.1091 and 2.1093 of this chapter except as specified in paragraphs (c) and (d) of this section.

(3) In general, when the guidelines specified in §1.1310 are exceeded in an accessible area due to the emissions from multiple fixed transmitters, actions necessary to bring the area into compliance are the shared responsibility of all licensees whose transmitters produce, at the area in question, power density levels that exceed 5% of the power density exposure limit applicable to their particular transmitter or field strength levels that, when squared, exceed 5% of the square of the electric or magnetic field strength limit applicable to their particular transmitter. Owners of transmitter sites are expected to allow applicants and licensees to take reasonable steps to comply with the requirements contained in §1.1307(b) and, where feasible, should encourage co-location of transmitters and common solutions for controlling access to areas where the RF exposure limits contained in §1.1310 might be exceeded.

(i) Applicants for proposed (not otherwise excluded) transmitters, facilities or modifications that would cause non-compliance with the limits specified in §1.1310 at an accessible area previously in compliance must submit an EA if emissions from the applicant's transmitter or facility would result, at the area in question, in a power density that exceeds 5% of the power density exposure limit applicable to that transmitter or facility or in a field strength that, when squared, exceeds 5% of the square of the electric or magnetic field strength limit applicable to that transmitter or facility.

(iv) Renewal applicants whose (not otherwise excluded) transmitters or facilities contribute to the field strength or power density at an accessible area not in compliance with the limits specified in §1.1310 must submit an EA if emissions from the applicant's transmitter or facility results, at the area in question, in a power density that exceeds 5% of the power density exposure limit applicable to that transmitter or facility or in a field strength that, when squared, exceeds 5% of the square of the electric or magnetic field strength limit applicable to that transmitter or facility.

(4) Transition Provisions: Applications filed with the Commission prior to October 15, 1997 (or January 1, 1998, for the Amateur Radio Service only) for construction permits, licenses to transmit or renewals thereof, modifications in existing facilities or other authorizations or renewals thereof require the preparation of an Environmental Assessment if the particular facility, operation or transmitter would cause human exposure to levels of radiofrequency radiation that are in excess of the requirements contained in paragraphs (b)(4)(i) through (b)(4)(iii) of this section. In accordance with §1.1312, if no new application or Commission action is required for a licensee to construct a new facility or physically modify an existing facility, e.g., geographic area licensees, and construction begins on or after October 15, 1997, the licensee will be required to prepare an Environmental Assessment if construction or modification of the facility would not comply with the provisions of paragraph (b)(1) of this section. These transition provisions do not apply to applications for equipment authorization or use of mobile, portable and unlicensed devices specified in paragraph (b)(2) of this section.

(i) For facilities and operations licensed or authorized under Parts 5, 21 (Subpart K), 25, 73, 74 (Subparts A, G, I, and L) and 80 of this chapter, the "Radio Frequency Protection Guides" recommended in "American National Standard Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 300 kHz to 100 GHz", (ANSI C95.1-1982), issued by the American National Standards Institute (ANSI) and copyright 1982 by the Institute of Electrical and Electronics Engineers, Inc., New York, New York shall apply. With respect to Subpart K of Part 21 and subpart I of Part 74 of this chapter, these requirements apply only to multipoint distribution service and instructional television fixed service stations transmitting with an equivalent isotropically radiated power (EIRP) in excess of 200 watts. With respect to Subpart L of Part 74 of this chapter, these requirements apply only to FM booster and translator stations transmitting with an effective radiated power (ERP) in excess of 100 watts. With respect to Part 80 of this chapter, these requirements apply only to ship earth stations.

(ii) For facilities and operations licensed or authorized under Part 24 of this chapter, licensees and manufacturers are required to ensure that their facilities and equipment comply with IEEE C95.1-1991 (ANSI/IEEE C95.1-1992), "Safety Levels With Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz." Measurement methods are specified in IEEE C95.3-1991, "Recommended Practice for the Measurement of Potentially Hazardous Electromagnetic Fields - RF and Microwave." Copies of these standards are available from IEEE Standards Board, 445 Hoes Lane, P.O. Box 1331, Piscataway, NJ 08855-1331. Telephone: 1-800-678-4333. The limits for both "controlled" and "uncontrolled" environments, as defined by IEEE C95.1-1991, will apply to all PCS base and mobile stations, as appropriate.

(iii) Applications for all other types of facilities and operations are categorically excluded from routine RF radiation evaluation except as provided in paragraphs (c) and (d) of this section.

(5) Existing transmitting facilities, devices and operations: All existing transmitting facilities, operations and devices regulated by the Commission must be in compliance with the requirements of paragraphs (b)(1) through (b)(3) of this section by September 1, 2000, or, if not in compliance, file an Environmental Assessment as specified in §1.1311.

(c) If an interested person alleges that a particular action, otherwise categorically excluded, will have a significant environmental effect, the person shall submit to the Bureau responsible for processing that action a written petition setting forth in detail the reasons justifying or circumstances necessitating environmental consideration in the decision-making process. (See §1.1313.) The Bureau shall review the petition and consider the environmental concerns that have been raised. If the Bureau determines that the action may have a significant environmental impact, the Bureau will require the applicant to prepare an EA (see §§1.1308 and 1.1311), which will serve as the basis for the determination to proceed with or terminate environmental processing.

(d) If the Bureau responsible for processing a particular action, otherwise categorically excluded, determines that the proposal may have a significant environmental impact, the Bureau, on its own motion, shall require the applicant to submit an EA. The Bureau will review and consider the EA as in (c) above.

(e) No State or local government or instrumentality thereof may regulate the placement, construction, and modification of personal wireless service facilities on the basis of the environmental effects of radio frequency emissions to the extent that such facilities comply with the regulations contained in this Chapter concerning the environmental effects of such emissions. For purposes of this paragraph:

(1) The term "personal wireless service" means commercial mobile services, unlicensed wireless services, and common carrier wireless exchange access services;

(2) The term "personal wireless service facilities" means facilities for the provision of personal wireless services;

(3) The term "unlicensed wireless services" means the offering of telecommunications services using duly authorized devices which do not require individual licenses, but does not mean the provision of direct-to-home satellite services; and

(4) The term "direct-to-home satellite services" means the distribution or broadcasting of programming or services by satellite directly to the subscriber's premises without the use of ground receiving or distribution equipment, except at the subscriber's premises or in the uplink process to the satellite.

Recommended Revision to proposed Section 95.603(f)

Language proposed to be added is shown in **bold underlined** text.

§ 95.603 Certification required.

* * * * *

(f) Each Medical Implant Communications Service transmitter (a transmitter that operates or is intended to operate in the MICS) must be certificated except for medical implant transmitters that are not marketed for use in the United States, but which otherwise comply with the MICS technical requirements and are operated in the United States by individuals who have traveled to the United States from abroad. <u>**Medical implant transmitters (as defined in Appendix 1 to Subpart E of Part 95 of this chapter) are subject to the radiofrequency radiation exposure requirements specified in §1.1307 and 2.1093 of this chapter, as appropriate. Applications for equipment authorization of devices operating under this section must contain a finite difference time domain (FDTD) computational modeling report showing compliance with these provisions for fundamental emissions. The Commission retains the discretion to request that specific absorption rate measurement data be also submitted.**</u>

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ATTACHMENT B

Literature search

The following summarizes the industry literature demonstrating FEM's recognition as a computational modeling tool of scientific value comparable to FDTD for human RF exposure testing purposes. Copies of each of the following identified articles and application notes are attached.

Exhibit A: "An International Inter-laboratory Comparison of Mobile Phone SAR Calculation with CAD-based Models," draft article in preparation for publication in an upcoming issue of the IEEE publication, Transactions on Microwave Theory and Techniques (MTT). Dr. Vogel is a co-author of this soon-to-be-released article comparing the calculation of head phantom SAR for three mobile phone brands. The geometries are realistic and complicated (see e.g. Figs. 1 and 5) **Fig. 7 compares the results of three different FDTD-based software tools and the Finite Element Method (FEM) based software package HFSS. HFSS is Lab 10 in this figure.** Significantly, the article demonstrates that FDTD-based simulation models produced a range of diverging results, while the FEM-based tool produced results well within the range of FDTD results. It can be concluded that the finite-element software produces results at least as accurate as FDTD software for average-SAR computations in a complicated and realistic configuration.

Exhibit B: "Towards the Validation of a Commercial Hyperthermia Treatment Planning System," Microwave Journal, December 2008. Once again, Dr. Vogel co-authored this analysis comparing simulation testing and laboratory measurements of hyperthermia radiation in the leg of an actual cancer patient. The simulations were done with HFSS coupled with thermal finite-element software. **HFSS is specifically identified as the simulation tool in the discussion following figure 3, which describes how the cancer treatment is simulated.** This discussion expressly addresses how simulation can be used to anticipate the SAR effects of treatment. **Of particular interest is the comparison between finite-element simulations and measurements shown in the "sidebar" at the end of this article.** Here, measured and FEM simulated temperatures of the subject tumor, resulting from electromagnetic absorption by in-vivo heterogeneous human tissue, are compared. **This comparison demonstrates that the measured and simulated temperatures closely track one another, particularly after 12 minutes into the experiment.** This demonstrates the validity of FEM for electromagnetic and thermal simulations in complicated and realistic heterogeneous human tissue.

Exhibit C: "Generic Phone SAR Comparison," October 17, 2008. This presentation to an IEEE Committee on electromagnetic safety demonstrates the comparable SAR results achieved by HFSS and a number of FDTD-based simulation tools for a generic dual-band mobile phone, held in a couple of different positions. This demonstration represents a large number of simulations, because each simulation was employed for two frequencies and for two positions in each frequency. **Reference to Ansoft (a subsidiary of ANSYS responsible for the development of HFSS) in this comparison is to HFSS.** Again, the presentation demonstrates the spread in results for a well defined model, even within the family of FDTD tools, produces a sizable uncertainty at both 900 and 1800 MHz. **The FEM results agree closely with the FDTD results.**

Exhibit D: "Strategies for Effective Use of EM Simulation for SAR", presented at the 2004 International Symposium on Electromagnetic Compatibility (Vol. 3, pages 864-867) by two Ansoft engineers. This paper focuses on a comparison of FEM simulations for SAR not only with FDTD tools but also with laboratory measurements. This was done for the configuration shown in Fig. 2, which is an often-used standard configuration by mobile-phone manufacturers. **As shown in Table 2, which lists the input impedance "seen" by the source, the agreement between HFSS results and measurements is good, generally closer than the relationship between FDTD and measurements. Indeed, HFSS results are more accurate in this case than FDTD results.**

Exhibit E: "Ansoft HFSS Analysis of Specific Absorption Rate for Flat Phantom Measurement Standard Outlined in IEEE P1528-2002." This is an internal Ansoft application note that compares FEM measurements with actual laboratory measurements, this time for a flat phantom, another standard configuration often used by mobile-phone manufacturers. **As can be seen in the first two plots, the measurement results practically coincide with the FEM results.** The table on page 1 contains the actual data illustrated in the plots.

Exhibit F: "SAR Assessment in a Human Head Model Exposed to Radiation from Mobile Phone Using FEM", presented at the 2002 IEEE International Symposium on Electromagnetic Compatibility (Volume 2, Pages 662–666), demonstrates the validity of FEM for the application of specific absorption rate (SAR) in heterogeneous head models, for radiation from cellular phones, by comparing with laboratory measurements and with independent results published by others (addressed in the document's references). The authors used realistic material properties for skin, bone and brain tissue as listed in Table 1 (p. 663) for human subjects and Table 2 (p. 664) for the case of rats. Table 3 (p. 665) compares FEM results with independent analytic results for a homogeneous case, and Table 4 (p. 665) compares FEM results with in-vivo measured results for rats. **Again, even in the complicated heterogeneous in-vivo case for a sophisticed, three-layer model presented in Table 4, the finite-element tool provided accurate SAR results (approximately 15% difference).** In this case, the FEM modeling tool was not HFSS.

Exhibit G: "Spatial Distribution of High-Frequency Electromagnetic Energy in Human Head During MRI: Numerical Results and Measurements", IEEE Transactions on Biomedical Engineering, Vol. 43, No. 1, January 1996, pp.88-94. This analysis, **particularly as illustrated in figure 4,** demonstrates the validity of FEM for heterogeneous tissues in electromagnetic fields generated by RF MRI coils. MRI images of the head of a human volunteer were used to construct a computer model of the geometry of the head, including its internal heterogenous structure. Subsequently, simulated MR fields in the head were compared with the measured fields. **Figure 4 shows an example of this comparison, in which the simulated results in figure (a) and the measured results in figure (b) demonstrated substantial agreement.** The authors of this analysis agree that the comparative results demonstrate a high level of agreement with one another.

Finally, a search for HFSS, ANSYS' finite-element based simulation tool, in the IEEE Xplore Digital Database yields more than 100 hits annually in recent years, indicating that this tool is widely used in the engineering community for many electromagnetic applications.

EXHIBIT A

An International Inter-laboratory Comparison of Mobile Phone SAR Calculation with CAD-based Models

Martin Siegbahn, Giorgi Bit-Babik, Jafar Keshvari, Andreas Christ, Benoît Derat, Vikass Monebhurrun, Christopher Penney, Martin Vogel, Tilmann Wittig

***Abstract*— An international inter-laboratory comparison for the calculation of head phantom SAR involving three mobile phones with CAD-based models has been conducted in order to evaluate the repeatability of such calculations and for providing input in the development of standardized procedures. SAR in the standardized SAM head phantom was calculated by ten laboratories in a blind study manner. The agreement in calculated SAR between the participating laboratories is very similar to the agreement obtained in inter-laboratory comparisons involving SAR measurements. This clearly shows that standardized procedures can be developed.**

***Index Terms*—FDTD methods, IEEE standards, simulation, software standards, specific absorption rate (SAR).**

I. Introduction

A. Background

THE progress of the area of electromagnetic simulation of complex dielectric structures has been rapid for the past few years with the introduction of full support for Computer Aided Design (CAD) models and hardware accelerator cards in several commercially available software packages. With these tools it is now possible to simulate the electromagnetic waves emitted from very detailed models of personal wireless communication devices and to evaluate the specific absorption rate (SAR) in standardized head and body models.

While procedures for experimental SAR evaluation of wireless devices have been available since several years as both national and international standards, for instance the IEEE Std. 1528 and IEC 62209-1, no standardized procedure for numerical SAR assessments has yet been developed. To address this, work was initiated in 2005 within the IEEE International Commission on Electromagnetic Safety Technical Committee 34, Sub-committee 2 (ICES TC34 SC2) to develop the IEEE 1528.1-4 series of standards for numerical SAR compliance testing of personal wireless devices. The selected numerical method for electromagnetic simulation for the 1528.1-3 standards is the FDTD method and for the 1528.4 standard the FEM method.

An important and to large extent remaining issue regarding computer simulation of electromagnetic fields and SAR for complex wireless devices is the total uncertainty in the produced results. Several studies have been published showing good or excellent agreement between simulation and measurement [1-3] but a general determination of the uncertainty has not yet been addressed. And, in order to complete standardized procedures an uncertainty evaluation has to be undertaken. Thus, as a first step, an investigation of the variation in produced SAR results as produced by several laboratories for the same tested device has been conducted.

B. International Numerical Inter-laboratory Comparison

An international numerical inter-laboratory comparison was designed in a similar way as in [4] where a number of laboratories calculated SAR in different head models for a simplified phone model in order to evaluate the conservativeness of the Specific Anthropomorphic Mannequin (SAM) head phantom. In this inter-laboratory comparison, however, only the SAM head phantom was used and instead of the simplified phone model three CAD models representing commercially available mobile phone models were included. By using highly detailed and complex CAD models the repeatability and reliability of numerical SAR evaluation of real devices was investigated. As a second important outcome of the inter-comparison, the experiences in conducting the calculations provided input in the development of standardized procedures.

Included in the IEEE 1528.3 standard for numerical SAR compliance testing of personal wireless devices is a set of benchmark validation problems. One of the problems constitutes a CAD model of simplified mobile phone, the so called Generic CAD phone model. It has the same basic

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features as the models used in the inter-laboratory comparison but with fewer components and with a lower complexity. Since it is only a software model without any real physical representation no measurement SAR data can be obtained. As an extension to the inter-laboratory comparison a number of the participating laboratories calculated SAR values for this model to be supplied in the IEEE 1528.3 standard as reference values.

II. Materials and Methods

A. CAD models of mobile phones

For the inter-laboratory comparison, CAD files representing three different commercially available mobile phone models were provided each by Motorola Inc, Nokia OY and Sony Ericsson Mobile Communications AB (See Figures 1, 2 and 3). The dielectric parameters of the materials of the SAM head phantom model were the international standard parameters. The parameters for the materials in the phone models were provided by the manufacturers.

Fig 1. The CAD model of the Motorola d30 phone model.

Fig 2. The CAD model of the Nokia 8310 phone model.

Fig 3. The CAD model of the Sony Ericsson W810 phone model.

The complexity of the CAD models representing the phone devices are somewhat different; in the Nokia model the printed circuit board (PCB) is modeled as a sandwich structure of thin sheets of metal and dielectric solids whereas in the Motorola and S-E phone models one metallic solid represents the PCB. Furthermore, in the Nokia model all components on the PCB were included. All three phone models have integrated patch antennas in the top back side part of the device. The antenna in the Sony-Ericsson phone model has a feature that poses an additional difficulty in the electromagnetic simulation; a parasitic element that has no galvanic contact to the other part of the antenna. This antenna element is resonant for the 1800 MHz band.

Dielectric parameters for the plastic materials of the Motorola phone were in the range 2.1 to 4.78 for the relative permittivity and 0.06 to 0.54 for tan δ. Corresponding figures for the Nokia were 2.5 to 3.3 for the relative permittivity and 0.00012-0.0068 S/m for the conductivity at 900 MHz and 0.00024-0.013 S/m for the conductivity at 1800 MHz. For the Sony Ericsson phone model the plastic materials had a relative permittivity of 2.7 and a tan δ of 0.007 at 1 GHz.

The benchmark model developed for the IEEE 1528.3 standard is a CAD model of a generic phone device that has no hardware representation. It resembles a real mobile phone but it is simplified in order to enable easy distribution with the standard. Yet, the physical properties of the model are still sufficiently complex so that it can not be drawn by hand in the electromagnetic solver. It has to be imported from file. This generic CAD model is shown in Figure 4.

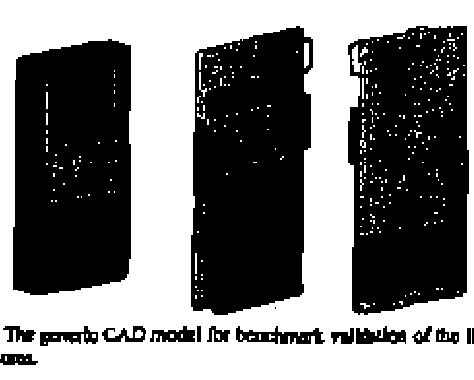

Fig 4. The generic CAD model for benchmark validation of the IEEE 1528.3 procedures.

B. Computational electromagnetics software

Ten laboratories conducted the calculations, in a blind-study manner, with five different commercially available software packages; CST MICROWAVE STUDIO® and CST MICROSTRIPES™ by CST AG, SEMCAD X® by Schmid & Partner Engineering AG, XFdtd® by Remcom Inc and HFSS by Ansoft LLC.

CST MICROWAVE STUDIO [Tilmann add text].

SEMCAD X is a universal simulation platform with a high-end ACIS® based modeler CAD importer and graphical user interface (in-house 3-D OpenGL renderer) that integrates various solvers providing native 64 bit functionality, such as full-wave EM solvers (C-FDTD, C-ADI-FDTD, etc.), FEM based low frequency and static solvers, thermal solvers for thin conductors, vessel trees, etc., coupled full-wave EM-SPICE circuit solvers and a GA based optimization platform. By combining SEMCAD X with Acceleware's [4] latest Nvidia GPU CUDA) based high performance systems, e.g. the ClusterInABox (CIB), simulations can be performed multiple hundred times faster than on a common desktop multi-processor machine. Finally, a postprocessing engine and Python scripting allows for result extraction/visualization (time- and frequency-domain, near-/far-field) and automation in general.

XFdtd is a software tool based on the Finite Difference Time Domain method. For this study, a variable meshing algorithm is used which increases the resolution for certain portions of the geometry while permitting lower resolution in other regions. The XFdtd computational engine uses uni-axial perfectly matched layers at the outer boundaries and hardware acceleration for increased performance. The software uses a custom-designed editing interface built on top of the industry-standard ACIS graphical toolkit.

HFSS employs edge-based vector finite elements on an unstructured mesh. The mesh elements are of non-uniform size, small in regions with small details, and up to a sizeable fraction of the local wavelength in uniform regions. The implementation of the finite-element method employs hierarchical basis functions, which allows elements to be as large as two-thirds of a wavelengths for the highest-order basis functions in uniform regions.

C. Calculations

Calculations of radiated electromagnetic fields from the phone models were conducted in free-space and when the models were positioned at the right ear of the standardized SAM head phantom [5] in the cheek and +15° tilt phone positions. Figure 5 and 6 shows the positions of the phone at the SAM head phantom. SAR, absorbed power in the head phantom and source impedance was calculated at one specific frequency in both the 900 MHz and 1800 MHz bands. The benchmark CAD model was calculated for the same test positions as the CAD models of the real phones.

Fig. 5. The CAD model of the Sony Ericsson W810 phone at the right ear of the SAM phantom in the cheek position.

Fig. 6. The CAD model of the Sony Ericsson W810 phone at the right ear of the SAM phantom in the +15° tilt position.

III. Results and Discussion

In Figures 7, 8 and 9 the calculated 10g averaged SAR results for all three phone models are presented as percentage of the mean result for each specific calculated setup, i.e. phone model, frequency and position at the SAM. All SAR results are normalized to the source output power. Even though all laboratories obtained the three CAD models of the phones, for various reasons a few laboratories could only produce SAR results for one or two of the models. Lack of time and computational resources was the most significant reason. Some laboratories reported problems in importing the CAD model as a reason for not being able to complete calculations even though they used the same software as other labs that were able to complete all calculations.

For the SAR results with the Motorola phone model, seen in Figure 7, the variation between the laboratories is higher for the lower calculated frequency, i.e. for 915 MHz, than for the higher frequency. For the Nokia phone model the variation in SAR is slightly higher for the high band simulations, as seen in Figure 8. However, the agreement is very good for the 902.4 MHz frequency and the cheek phone position were all results are within 15% of the mean. This is somewhat surprising considering the higher complexity of the Nokia model with a more detailed representation of the PCB. The variation between the laboratories in the SAR results for the Sony Ericsson phone model is similar for both computed carrier frequencies. The maximum relative standard deviation for the Motorola phone model SAR results is 30%. For the SAR results obtained with the Nokia and Sony Ericsson phone models the corresponding maximum relative standard deviations are 20% and 25%, respectively.

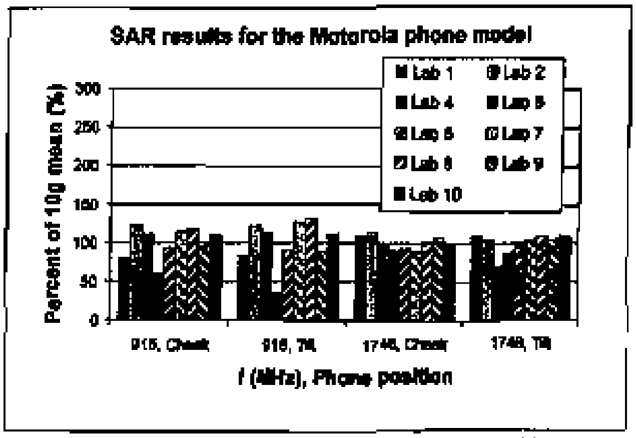

Fig 7. The 10g SAR results for the Motorola c330 phone model in percent of the mean result for each calculated configuration.

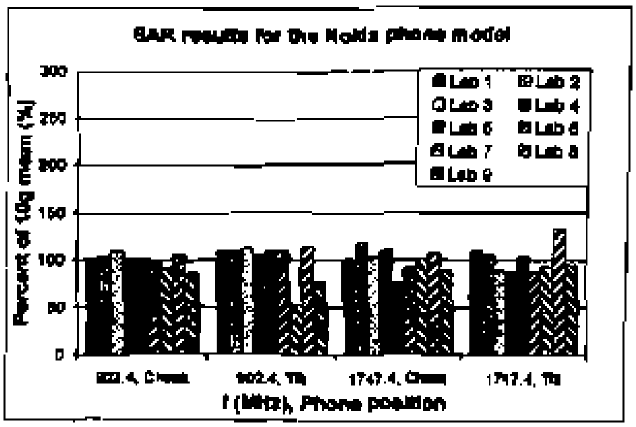

Fig 8. The 10g SAR results for the Nokia 6310 phone model in percent of the mean result for each calculated configuration.

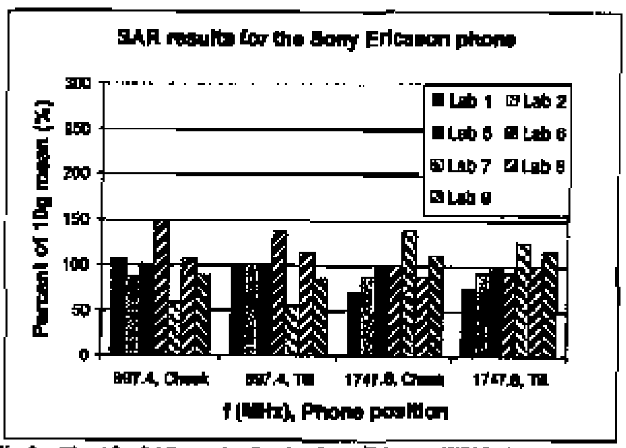

Fig 9. The 10g SAR results for the Sony Ericsson W810 phone model in percent of the mean result for each calculated configuration.

A Cumulative Distribution Function (CDF) was computed for all the deviations from the mean SAR results and is shown in Figure 10. The 95-percentile is about 40% for both the 1g and 10g averaged SAR results. The variation for the Motorola and Sony Ericsson models are higher than for the Nokia model possibly indicating a higher sensitivity to differences in the simulation parameters such as meshing, simulation time, etc. Other sources of deviations include positioning errors of the phone at the phantom, source model simplifications, location of simulation boundaries and numerical method approximations. Human errors can of course also be present considering the high complexity of the CAD models.

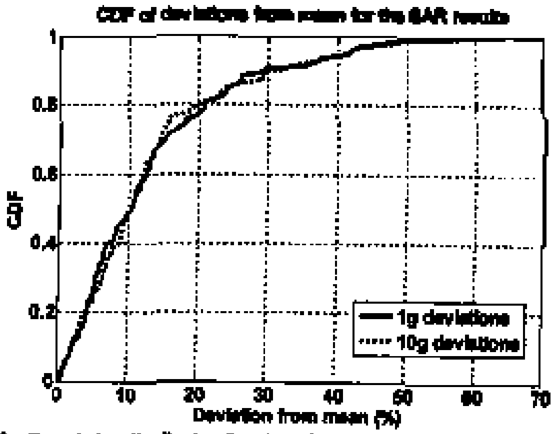

Fig. 10. Cumulative distribution functions for the deviations from mean for the 1g and 10g SAR results

A number of submitted values deviated 50% or more from the mean results and could thus be considered as out-layers. A detailed analysis was conducted in order to identify the causes for these out-laying values since they would provide very valuable input in the drafting of standardized procedures. The out-layers considered in this analysis are the following values; the value from laboratory 5 for the Motorola phone for the tilt phone position and 915 MHz carrier frequency, the value from laboratory 7 for the Nokia model for the tilt position and 902.4 MHz frequency and the laboratory 6 value for the Sony Ericsson phone model for the cheek position and the 897.4 MHz frequency. Also both the values from the laboratory 7 for the 897.4 MHz frequency are very low compared to the other submitted results and could be considered as out-layers. The laboratory 5 value deviates about 65% from the mean results which is the largest deviation observed. An in-depth analysis conducted by laboratory itself of the grid used in this calculation showed that the grid around the antenna had been assigned a too coarse grid step by mistake. When the grid step was set for the SAM phantom this coarser grid setting had unintentionally propagated to the region surrounding the antenna. When a finer grid step was used for the antenna and the calculation repeated a SAR result deviating only 23% from mean was obtained. Similarly, laboratory 6 also found that a too coarse grid step had been used for antenna. With this grid step the gap between the main antenna element and the parasitic element was only modeled with one grid step and thus the tangential antenna currents in the gap were not calculated. Finally, laboratory 7 found that the deviating values it had submitted for the Sony Ericsson phone model were due to a wrong setting of the dielectric parameters of the SAM head phantom. In conclusion, the out-layer values were thus either due to a too coarse grid-step chosen for the antenna or operator error in setting the material parameters.

As an additional part of the out-layer analysis it was decided to produce source point impedance in order to evaluate the overall quality of the grids used. The hypothesis was that if the calculated FDTD grids could produce accurate source point impedance results with good agreement between the laboratories then the SAR results would also show good agreement. In other words, to investigate if there is a correlation between the impedance and SAR results. The procedures for these additional calculations were such that the grids used for the cheek position simulations were used but with the material parameters for the SAM phantom set to air instead. In that way the free-space impedance was obtained but with the same grids as used for the head phantom simulations. Figure 11 shows the calculated source point s11 in dB for the Motorola phone model. It is clear that the impedance results show a considerable variation that is difficult to correlate to the SAR results seen in Figure 7 for the 900 MHz band simulations.

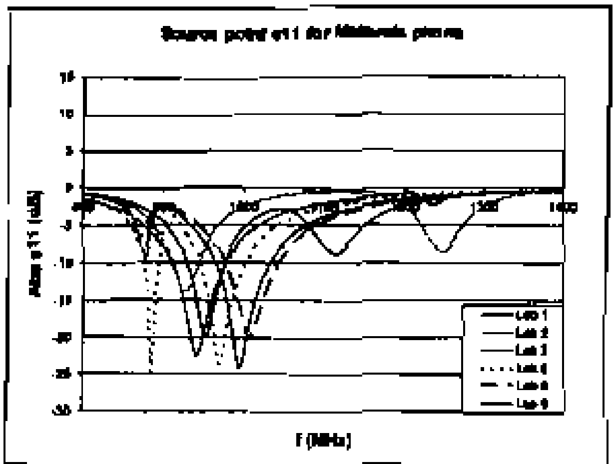

Fig 11. The source point s11 for the Motorola phone model

On the other hand, in Figure 12 the impedance results for the 900 MHz band for the Nokia phone model are presented. Here the agreement in calculated s11 is very good between the participating laboratories. Also the agreement in SAR between those laboratories who have submitted this impedance data is remarkably good. Thus, from the results obtained it can not be clearly concluded whether agreement in impedance results leads to consistent SAR results.

Finally, the SAR results for the benchmark CAD model are displayed in Figure 13. As seen in the figure, the agreement is remarkably good. The largest deviation from mean is here about 20% which is well in line with deviations normally observed in SAR measurements. The results obtained with this benchmark model show the kind of agreement that most probably can be obtained in calculations with a real phone model if standardized procedures are used and care has been taken to avoid the errors that occurred in the previously described inter-comparison with CAD models of real phones. It is thus again proven that reproducible results are possible to obtain motivating the development of standardized procedures.

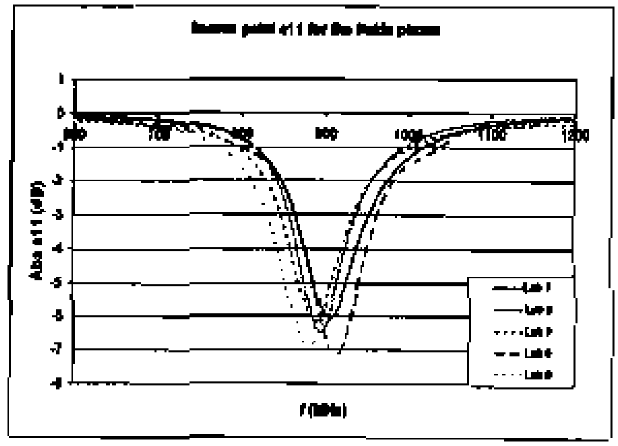

Fig. 12. The source point s11 for the Nokia phone model.

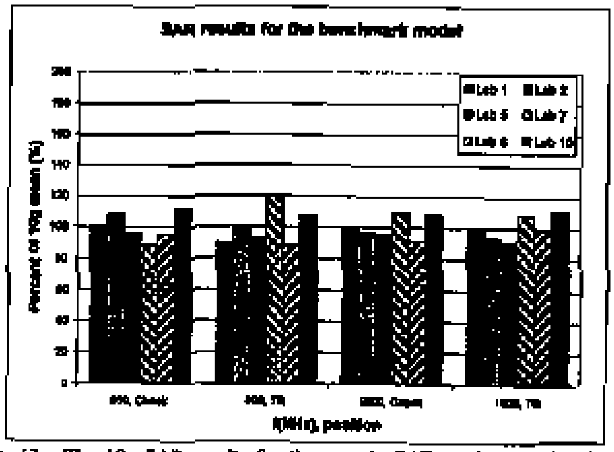

Fig. 13. The 10g SAR results for the generic CAD model intended for benchmark validation in IEEE 1528.3. The results are displayed as percent of the mean result for each calculated configuration.

A question that is of course relevant in the context of the conducted inter-comparison is how the calculated SAR results compare to corresponding measurement results for the used phone models. That question has in principle not been addressed since a number of simplifications were made to the used CAD models and they thus not fully represent the real device. Additionally, and most important, the dielectric parameters for some of the plastic parts of the models were assigned values that were taken from literature rather than actual values for the used materials.

IV. Conclusion

The agreement in calculated SAR between the participating laboratories is very similar to the agreement obtained in inter-laboratory comparisons involving SAR measurements. This shows that reproducible results are possible to obtain and it motivates the further development of standardized procedures for numerical SAR testing of mobile phones. Sources for the observed deviations have been identified and recommendations on how to deal with them as part of an uncertainty evaluation will be included in the IEEE 1528.3 standard.

ACKNOWLEDGMENT

The authors wish to thank Omid Sotoudeh, formerly at Sony Ericsson Mobile Communications AB, for providing and preparing the CAD model of the Sony Ericsson phone model.

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Martin Vogel received his M.Sc. degree in Physics from Leiden University in 1985 and his PhD in Electromagnetics from Delft University of Technology in 1991. He worked at TNO Defense and Security in the Netherlands from 1985 until 1996 on applications involving, among other things, radar cross section. In 1996 he had a one-year assignment at Kirtland Air Force Base in New Mexico, after which he joined Ansoft LLC. There, as a Sr. Member of the Technical Staff, he has worked on a wide variety of high-frequency applications.

Thomas Wittig was born in Leverkusen, Germany, in 1972. He received his Dipl.-Ing. degree in telecommunications and his Ph.D. in electromagnetic simulation technology from the Technical University of Darmstadt, Germany, in 1998 and 2003. In 2004 he joined the CST AG, where he works as a Senior Application Engineer in the areas of antenna and bio-medical simulations as well as computational dosimetry.

EXHIBIT B

December 2008 Issue: Cover Feature

Towards the Validation of a Commercial Hyperthermia Treatment Planning System

Demonstration of the capabilities of a suite of electromagnetic and thermodynamic simulation tools for external hyperthermia treatments with a radio frequency phased-array heat applicator

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Recent developments have reinvigorated clinical investigations of hyperthermia (HT) as a viable adjuvant treatment in the fight against cancer. Researchers are placing a greater emphasis on multi-modal approaches that include mild temperatures (40° to 43°C) and standard therapies like radiation and chemotherapy, than on achieving higher temperature treatments (43° to 45°C), which were pursued in the past.

The emergence of robust computer simulation tools for accurate hyperthermia treatment planning has aided this resurgence by helping improve the quality of heating. This article outlines a recent collaborative study at Duke University to demonstrate the capabilities of a new suite of 3D electromagnetic and thermodynamic simulation tools for treatment planning of external hyperthermia treatments with a radio frequency (RF) phased-array heat applicator. Following a brief introduction to the rationale for moderate temperature hyperthermia and current methodology for heating tissue at depth in the body, the article will present a new approach for improved heating based on treatment planning with electromagnetic simulation software tools. Procedures, benefits and a comparison of simulated heating patterns with those measured in two clinical hyperthermia treatments of advanced fibrous histiocytoma (soft-tissue sarcoma) tumors will be presented.

Historical Background

Modern interest in hyperthermia began in the second half of the 19^{th} century with a serendipitous clinical observation that some patients with externally visible tumors who experienced even moderate systemic temperature rise from a separate, severe illness experienced remissions of their tumors.[1] Although intriguing, subsequent studies of fever induced therapy gave way around the turn of the century to a more intense interest in the oncological potential of the then newly discovered Roentgen Rays (X-rays). By the 1970s, frustrated with the limited success of radiation therapy for some resistant tumors, researchers returned to studies of the cell killing potential of heat as an adjuvant therapy to enhance the effects of radiation.[2] By 1984, hyperthermia was an approved medical treatment for superficial tumors that could be heated with the equipment available at that time.

New Biological and Clinical Rationale

Bolstered by research in the 1980s emphasizing the cell killing potential of heat, researchers focused on high temperature hyperthermia (> 43°C) treatments intended to induce cell death. Unfortunately, this approach was limited by a number of biological, technological and commercial factors. As a result, interest in hyperthermia suffered a setback in the mid-1990s.[1] Fears of thermotolerance, for example, limited the number of heat fractions to about two per week. Thermotolerance in surviving cells increases with temperature; however, its effect is now known to be limited in tissues treated with mild-temperature HT.

Heating tissue above 43°C also causes vascular damage, thereby inducing hypoxia, whereas the presence of oxygen is critical to the effectiveness of both radiation- and chemo-therapies. It is now understood that mild HT leads to increased blood perfusion and pO2 (reoxygenation) of fast-growing hypoxic tumors that have outgrown their local blood supply, thus enhancing radio- and chemo-sensitization. Furthermore, because of the threat of vascular damage and hypoxia, heat was often applied after radiation, which can reduce the effectiveness of the HT in terms of reoxygenation. Finally, studies have shown that mild HT results in the denaturation (unfolding) and eventual aggregation of nuclear proteins, processes that interfere with mitosis, DNA transcription and DNA repair.

A noted absence of detrimental clinical effects of thermotolerance and overwhelming evidence of positive effects from tissue reoxygenation and increased denaturation/aggregation potential are the key biological factors encouraging scientists to rethink adjuvant mild hyperthermia.

Accompanying Technological and Commercial Considerations

A typical course of clinical hyperthermia treatments consists of four to eight heating sessions, spread over a period of several weeks. The first hour of a two-hour session is used for patient preparation, such as placement of thermal monitoring probes in and around the tumor volume and the placement of the RF applicator around the tumor region. After the patient is prepared, power is supplied to the applicator's antenna(s) and the tumor is heated by radiated electromagnetic energy.[4]

Though the principles of tumor heating are widely understood, the technology to focus heat into a desired tumor volume at depth in the body has lagged behind the theory, especially for deep-seated malignant tumors. For regional hyperthermia of deep-seated tumors, electromagnetic annular phased-array applicators (including smaller sized mini-annular phased-array (MAPA) applicators that fit around one extremity) have been developed for the frequency range of 75 to 150 MHz.[5-7] To focus the heat into the tumor site, researchers have found that the driving phases and amplitudes of the MAPA must be carefully controlled.

Equipment considerations also damaged initial perceptions of hyperthermia and have significantly slowed acceptance of this clinical modality. Limited adjustability of applicator power deposition patterns led to poor control of heating, which has restricted the number of locations to which HT could be reliably applied. Even for multiple antenna arrays, inflexible and clunky controls made beam focusing and steering slow and imprecise. Delivering the required power to the target also presented a challenge. The absence of robust computer simulations often left clinicians to deal with superficial "hot spots"—in some cases leading to undesirable blisters or burns on the skin surface (air-dermis interface). The absence of noninvasive thermometry forced HT technicians to rely on a very limited number of implanted temperature probes. Insurance controlled cost codes and restrictive reimbursement rates have also played a role in encouraging OEMs to forego development plans. Happily, many of these technical challenges have been addressed in the last 10 years and promising solutions are emerging.

The Duke Study: Equipment, Methods and Results

Power Delivery System